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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,369	02/26/2004	Shozo Koyama	AMN-006-003	3406

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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,369	KOYAMA ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-46* is/are pending in the application.

4a) Of the above claim(s) *29-34,36 and 38-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath or Declaration

1. It is noted that PCT/JP98/00351 is recorded under "PRIOR FOREIGN APPLICATION(S)" in the declaration filed 2/26/04, however, a proper box (YES, NO) has not been checked for "PRIORITY CLAIMED UNDER 35 USC § 119".

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. With regard to claim 35, it is unclear what compounds are intended to encompass by the term "vaccine precursor".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is directed to a method fo prophylaxis and/or therapy of a cancer comprising administering a

vaccine prepared by treating cells of said cancer with a compound of formula 3-a or prepared from a vaccine precursor by treating the cells of said cancer with a compound of formula 3-a. The subject matter was not described in the specification in such a way as to one of skilled in the art could reasonable tell what is a vaccine precursor how the precursor can be use as vaccine for cancer. "Vaccine" is an antigenic preparation to establish immunity in and animal in order to prevent disease from occurring. An the term "prophylaxis" is a term refers to medical or public health measures take in order to provent disease or health problem. None of this have been shown with the compound of formula 3-a. Prevention or propahylaxis from cancer have not been described or disclosed in the specification and thus the compound cannot be regarded as vaccine or the compound cannot be regarded as a compound for prophylaxis. As described in the specification "Yoshixol" (i.e. the compound of claim 35 wherein all of R_3, R_4, R_5 and R_6 are hydrogen) is shown to inhibit growth of a cancer and/or improve survival time of a mice having cancer by administering a composition which comprises sediment of extinct cells of said cancer prepared by treating said cells of cancer with Yoshixol wherein said cancer is leukemia or melanoma (see pages 40-42). As described in the specification, the composition is either administered in an animal (mice) that already have cancer to show increase in survival time or administered to a mice implanted with cancer cells to show improvement in the inhibition of cancer growth. However, none of the experiment show "prevention" of cancer or the substance (composition) used as prophylaxis for prevention of cancer. Moreover, the only compound used to show

improvement of survival time or improvement of cancer growth is Yoshixol. Not a single derivative of the compound is suggested or used in any experiment to show any effect with regard to cancer growth or survival time. Since a substitution in a compound can greatly change its reactivity and immunogenicity, without a clear experimental evidence, all derivatives of a compound cannot be generalized to declare as a drug for cancer therapy. There is no clear description in the specification about what compound(s) in the composition is responsible for improving the survival time or cancer growth. There is not mechanism of suggested mechanism disclosed in the specification that provides the intended function. Furthermore, the experiment is restricted to rodents and no experiment was done in mammals and thus improvement in survival rate or cancer growth cannot be generalized to all animals.

Therefore, an artisan in the art would not be able to practice the invention because an undue experimentation will be required to judge suitability of the compound and its derivatives as "vaccine" for cancer or suitability of the compound to prevent cancer growth and/or improve survival time of other animals (e.g. mammals) except a mice. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Response to argument

7. Applicant's arguments filed 7/26/07 have been fully considered, and are persuasive to overcome the rejections under 35 USC 112 first and Second paragraph, but Applicants arguments are rendered moot in view of new grounds of rejection as described in this office action necessitated by Applicants' amendment.

Conclusion

8. Applicants' amendment necessitated new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support

for the claimed invention (e.g., if the amendment is not supported in ipsis verbis, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
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